510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE AND INSTRUMENT TEMPLATE

A. 510(k) Number:
K033688

B. Purpose for Submission:
Clearance of data management software for their cleared H_2 breath meter (K963376)

C. Analyte:
Breath hydrogen gas

D. Type of Test:
Electrochemical

E. Applicant:
Micro Direct, Inc.

F. Proprietary and Established Names:
Micro H2 Breath Monitoring Device with Hydra Software Utility

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862. 1820, Xylose test system
2. Classification:
   Class I
3. Product Code:
   NRH, System, breath management
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

The Micro H_2 is intended to be used in the screening and diagnosis of lactose malabsorption, a condition that produces increased hydrogen levels in the blood when unabsorbed lactose reacts with bacteria in the intestines. This increased level of hydrogen is expired and can be measured after ingestion of lactose following a period of fasting.

2. Indication(s) for use:

See intended use above.

3. Special condition for use statement(s):

For professional use only

4. Special instrument Requirements:

Micro H2 Breath Monitoring Device
Personal computer using Windows OS

I. Device Description:

The device consists of a hand-held hydrogen breath monitor (cleared as K963376) that is connected to a personal computer (PC) via a serial communications cable. A software utility on the PC then acquires and logs successive breath measurement data from the hydrogen monitor. The software also has data analysis and organization functions.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Micro H2 Breath Monitoring Device
2. Predicate K number(s):
   K963376
3. Comparison with predicate:
   The device and the predicate share the same intended use, methodology, and performance. The only difference is the addition of a software utility to aid the user in data recording, management, and analysis.

K. Standard/Guidance Document Referenced (if applicable):

FDA Guidance Document - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

ISO 13485:1996
EN 1441
ISO 14971-1, Part 1
IEC/EN 60601-1-4, Part 1 number 4

L. Test Principle:

Same as in K963376.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   - *a. Precision/Reproducibility:*
     Not applicable in this submission. See K963376.
   - *b. Linearity/assay reportable range:*
     Not applicable in this submission. See K963376.
   - *c. Traceability (controls, calibrators, or method):*
     Not applicable in this submission. See K963376.
   - *d. Detection limit:*
     Not applicable in this submission. See K963376.
   - *e. Analytical specificity:*
     Not applicable in this submission. See K963376.
   - *f. Assay cut-off:*
     Not applicable in this submission. See K963376.

2. Comparison studies:
    a. *Method comparison with predicate device:*
    Not applicable in this submission. See K963376.
    b. *Matrix comparison:*
    Not applicable in this submission. See K963376.
3. Clinical studies:
    a. *Clinical sensitivity:*
    Not applicable in this submission. See K963376.
    b. *Clinical specificity:*
    Not applicable in this submission. See K963376.
    c. *Other clinical supportive data (when a and b are not applicable):*
    Not applicable in this submission. See K963376.
4. Clinical cut-off:
    Not applicable in this submission. See K963376.
5. Expected values/Reference range:
    Not applicable in this submission. See K963376.

N. Instrument Name:

Hydra Software Utility for use with the Micro H_2 Breath Monitoring Device

O. System Descriptions:

1. Modes of Operation:
    Automatic – automatically acquires breath H_2 measurements from monitor
2. Software: Operating system – Microsoft Windows (multiple versions)
    Microsoft Access-based database for data storage

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes __3____ or No _____

3. Sample Identification:
    Manual – patient ID entered manually, but software automatically logs sequential breath measurements for the patient
4. Specimen Sampling and Handling:
    Not applicable, patient breathes directly into monitoring device
5. Assay Types:
    Chemistry
6. Reaction Types:
    Electrochemical
7. Calibration:
    The software utility requires no calibration
8. Quality Control:
    Quality control procedures are recommended for the monitor. No quality control by the user is necessary for the software utility

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Determination Decision Summary:

Not applicable

Q. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.